UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/619,310 | 07/19/00 | THASTRUP O | 114465.401 |

021269
PEPPER HAMILTON
600 FOURTEENTH STREET NW
WASHINGTON DC 20005

HM12/0911

| EXAMINER | |
|---|---|
| UNGAR,S | |
| **ART UNIT** | **PAPER NUMBER** |
| 1642 | 4 |

**DATE MAILED:** 09/11/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/619,310 | Thastrup et al |
| **Examiner** | **Art Unit** |
| Ungar | 1642 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Jun 4, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-37* are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

1. Claims 1-37 are pending in the application and are currently under prosecution.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CAR 1.8821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CAR 1.821 through 1.825 for the reasons(s) set forth on the attached Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Although Applicant has submitted a Verified Statement under 37 CFR 1.821(f), no CRF has been received by this office for the instant application. If the CRF is identical to that submitted in Application No. 08/819,612, Applicant must submit a statement to that effect and request the use of that CRF, in accordance with 37 CAR 1.821(e), in the instant application.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer from the date of this letter within which to comply with the sequence rules, 37 CAR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821 (g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CAR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

**Group I.** Claims 1-7, 23-26 are drawn to a fluorescent protein derived from Fluorescent Protein classified in Class 530, subclass 350.

**Group II.** Claims 8-9, 32 are drawn to a fusion compound consisting of Fluorescent Protein linked to a polypeptide, classified in Class 530, subclass 402.

**Group III.** Claims 10-17, 27-31, 33 are drawn to a nucleotide sequence encoding for Fluorescent Protein, a DNA construct comprising the nucleotide sequence encoding Green Fluorescent Protein and a suitable control region or regions, a host cell transformed with the construct and a process for preparing a Fluorescent Protein, classified in Class 536, subclass 23.1 and Class 435, subclass 320.1.

**Group IV.** Claim 18 are drawn to an in vitro method for measuring protein kinase activity with the Green Fluorescent Protein in a cell extract, classified in Class 435, subclass 4.

**Group V.** Claim 19 is drawn to an in vivo assay method for measuring metabolic activity, classified in Class 424, subclass 93.1.

**Group VI.** Claims 20, 21, 34-37 are drawn to a method for reporting gene expression in living cells classified in Class 435, subclass 6.

**Group VII.** Claim 22 is drawn to a method of tagging organelles or cell processes, classified in Class 435, subclass 4.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III represent chemically distinct products, obtained by and used in different methods.

The inventions of Groups III-VII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups I and IV/VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the protein product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the fusion compound as claimed can be used in a materially different process such as affinity chromatography.

The inventions of the host cell of Group III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the

following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the host cell product as claimed can be used in a materially different process such producing purified florescent protein for the stimulation of antibody production.

The inventions of Groups I and V are not at all related because the protein of Group I is not used in any of the methods of Group V.

The inventions of Groups II and IV/V/VII are not at all related because the fusion compound is not used in any of the methods of Groups IV/V/VII.

The inventions of Groups III and IV, VI, VII are not at all related because the nucleic acid of Group III is not used in any of the methods of Groups IV/V/VII.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of patentably distinct species comprising variants of Florescent Proteins with different structures and functions where in the species are from different species with different chromophores, different variations in chromophores, different variations in the amino acid in position 1 preceding the chromophore and different sequences as shown in the figures. Applicant is required

to elect a single defined green fluorescent protein with defined parameters for examination as the elected species.

7. Group II is further subject to election of a single disclosed species.

(I) Claim 9 is generic to a plurality of disclosed patentably distinct species comprising fusion proteins with different structures and function wherein the polypeptide is (a) a kinase or (b) a cytoskeletal element.

(ii) Claim 9 is further subject to election of a single disclosed patentably distinct species with different structures and functions wherein the polypeptide is the catalytic subunit of (a) protein kinase A, (b) protein kinase C and (c) Erk1. The species of Section ii will be examined if Species (a) of Section i is elected.

8. Group III is further subject to election of a single disclosed species.

(I) Claim 10 is generic to a plurality of disclosed patentably distinct species wherein the Fluorescent Protein has different structures and functions wherein the nucleotide sequences are shown in (a) Fig 3, (b) Fig 4 and (c) Fig 5, all of claim 11. Further, claim 10 is generic to a plurality of patentably distinct species comprising nucleotides comprising variants of Florescent Green Proteins with different structures and functions where in the species have different chromophores, different variations in chromophores, different variations in the encoded amino acid in position 1 preceding the chromophore and different sequences as shown in the figures. Applicant is required to elect a single defined nucleotide sequence coding for the fluorescent protein with defined parameters for examination as the elected species.

(ii) Claim 13 is generic to a plurality of disclosed patentably distinct species wherein the DNA construct is under the control of different promoters including (a) native GFP promoter, (b) mammal constitutive promoter, (c) mammal regulatory promoter, © viral promoter, (d) yeast promoter, (e) filamentous fungi promoter and (f) bacterial promoter. Claim 17 will be examined if Species (a) of 5ii is elected.

(iii) Claim 15 is generic to a plurality of disclosed patentably distinct species wherein the host is selected from the following distinct organisms and cells (a) bacteria, (b) yeast, (c) fungi, (d) protozoans and (e) higher eucaryots.

9. Group V is further subject to election of a single disclosed species.

Claim 19 is generic to a plurality of disclosed patentably distinct species comprising assay of different cellular functions using different assay methods wherein the assays measure (a) kinase activity, (b) dephosphoylating activity, both of claim 19.

10. Group VI is generic to a plurality of disclosed patentably distinct species comprising the assay of different numbers of genes with different structure and function wherein the assay measures (a) one gene (claims 20, 34, 36), (b) more than one gene (claims 21, 35, 37). It is noted that the assays are drawn to Fluorescent Proteins which have different structures and functions wherein the nucleotide sequences encode different chromophores and wherein the position 1 upstream from the chromophore is different from the amino acid at the corresponding position in the wild-type GFP amino acid sequence. Applicant is required to elect a single defined fluorescent protein with defined parameters for examination as the elected species.

11. Group VII is generic to a plurality of disclosed patentably distinct species comprising visualization of different types of cell processes in different types of structures wherein the structures are (a) organelles, (b) whole cells, both of claim 22.

12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 308-305-2181.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, PhD, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4065.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar
Primary Patent Examiner
September 8, 2001